REMARKS

The application has been carefully reviewed in light of the Office Action dated March 11, 2003 and the Advisory Action dated May 24, 2002. Claims 1 to 5, 8 and 14 to 19 are in the application, of which Claims 1, 8, 14 and 15 are independent. Reconsideration and further examination are respectfully requested.

Claims 1 to 5, 8 and 14 to 19 were rejected under 35 U.S.C. § 101 and § 112, first paragraph. According to the Office Action, the claimed invention allegedly is not supported by either a specific and substantial asserted utility or a well-established utility. Consequently, one of skill in the art would not know how to use the invention. Rather than repeat the basis of the rejections, the Office Action refers to arguments set forth in previous Office Actions. Applicants respectfully traverse the rejections.

The present invention, according to Claim 1, relates to an isolated polynucleotide having a coding sequence consisting of the nucleotide sequence of SEQ ID NO: 21, which is disclosed in the submitted sequence listing.

Claim 8 relates to an to an isolated polynucleotide having a coding sequence consisting of the CDNA insert of clone er311_20 deposited under accession number ATCC 98781.

Claim 14 relates to an isolated polynucleotide having a coding sequence consisting of the nucleotide sequence of SEQ ID NO:21 from nucleotide 8 to nucleotide 2008.

According to Claim 15, the present invention also relates to an isolated polynucleotide coding a sequence that encodes a protein consisting of the amino acid sequence of SEQ ID NO:22, which is also disclosed in the submitted sequence listing.

Applicants maintain that the claimed invention has at least one specific and substantial utility and a well-established utility based on its similarity in sequence to AF035526, which codes for a mouse kanadaptin protein. Based on this similarity, skilled artisans would expect the claimed invention to encode a protein which shares activity with mouse kanadaptin proteins. See pages 197 and 198 of the specification. Thus, at the very least, the claimed invention may be used to better characterize known kanadaptin proteins. It is clear that this asserted utility is not a "throw away" utility or a suggestion of further research on the claimed invention. Rather, the asserted utility is for use of the claimed invention as a tool to study other compositions.

As set forth in the Utility Guidelines published January 5, 2001, and quoted in the Advisory Action dated May 24, 2002, a statement of fact made by an applicant in relation to an asserted utility must be treated as true, unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement. The specification asserts a similarity between the claimed invention and AF035526 and predicts a shared activity between the encoded proteins. As of yet, the record reflects no evidence that would counter the Applicants' assertion.

The requirement to accept an applicant's assertions is not only present in the Utility Guidelines, but also has been recognized in case law. See In re Wright, 27 USPQ2d 1510 (Fed. Cir. 1993).

It appears from previous Office Actions that the asserted similarity has been dismissed based on the fact the "specification does not list the level of similarity or similarity parameters used to determine the level of similarity." However, it is not Applicants' burden to produce the level of similarity. No such requirement exists. Rather,

it is sufficient that Applicants have asserted that the level of similarity is such that shared activity can be predicted. Such an assertion, insofar as it relates to the utility of the present invention, must be taken as true unless there is evidence to the contrary.

Although no evidence has been offered to counter Applicants' assertion, it is argued in the Office Actions that a sequence similarity of less than 100% does not reasonably allow one skilled in the art to conclude that there is biochemical activity in the claimed subject matter. Applicants submit that such a statement is apparently contrary to the official positions taken by the Patent Office in other cases. As noted in a previous amendment, the Patent Office has issued more than 120 patents from 1996 to date, which contain the claim language "polynucleotide which hybridizes." By allowing such claims, the Patent Office is consistent with well-established scientific principles that recognize that hybridized sequences with similarities less than 100% also have biochemical activities akin to the original sequence. As such, it appears reasonable to have a sequence similarity that is less than 100%, and yet conclude that there is some biological or biochemical activity.

Once Applicants' assertion regarding sequence similarity and predicted biological activity has been accepted, as it must absent evidence to the contrary, the well-established utilities relating to kanadaptin are seen to follow.

Moreover, Applicants maintain their position that the Office Action has failed to establish a *prima facie* case of lack of utility. The Utility Guidelines published January 5, 2001 set forth the standard for establishing a *prima facie* case for lack of utility. Specifically, the guidelines allow for three different situations which might support a rejection for lack of utility: A) the asserted utility is not specific or substantial; B) the asserted specific and substantial utility is not credible; or C) no specific and substantial utility is disclosed or is well-established. It is not clear on which one of the three bases the

Office Action relies. Regardless, the record fails to establish even one of these bases and therefore the burden of establishing a *prima facie* case for lack of utility has not been met, as explained below.

The most recent Office Action alleges that the present invention has "no specific and substantial or well-known utility", leading Applicants to speculate that the rejection might be based on point C). Under point C), a *prima facie* showing of no specific and substantial utility must establish that applicant has not asserted a utility and that, on the record before the Examiner, there is no known well-established utility. In view of the arguments set forth above, it is clear that Applicants have asserted a specific and substantial utility and well-established utilities are known to exist based on the similarity to mouse kanadaptin. Thus, the burden under point C) has not been met and point C) does not apply.

The Advisory Action mentions the "credibility" of the utility, which has led Applicants to speculate that the rejection might be based on point B). Under point B), a *prima facie* showing of no specific and substantial credible utility must establish that it is more likely than not that a person skilled in the art would not consider credible any specific and substantial utility asserted by the applicant for the claimed invention. This has also not been established by any of the Office Actions of record. Indeed, the Advisory Action specifically concedes that this cannot be established:

> "It is not possible to provide documentary evidence that the claimed polynucleotides do not encode polypeptides that are useful as a polypeptide with kanadaptin activity."

As noted above, Applicants have asserted a similarity in homology to mouse kanadaptin that is sufficient to predict a shared activity. No evidence has been provided to challenge

this assertion and the reasons setting forth the rejection are seen to be improper, as discussed above. Therefore, the standard under point B) has not been met and point B) does not apply.

Since points C) and B) have not been established, any rejection for lack of utility must be established with point A). However, the burden under point A also has not been established.

In regards to point A), a *prima facie* showing must establish that it is more likely than not that person of ordinary skill in the art would not consider that any utility asserted by the applicant would be specific and substantial. Applicants have repeatedly asserted utilities which are specific and substantial. None of the Office Actions have established that any utility asserted by Applicants would not be specific and substantial. Thus, point A) also does not apply.

In view of the foregoing, Applicants respectfully request withdrawal of the § 101 rejection for lack of utility. Since the § 112, first paragraph rejection relating to use of the present invention is based on the alleged lack of utility, withdrawal of this rejection is also respectfully requested.

The Office Action dated March 11, 2003 refers to past rejections of Claims 1 to 5, 8, 14 and 16 to 19 under 35 U.S.C. § 112, first paragraph for alleged lack of written description. However, it is not clear from the Office Action whether these rejections are "is maintained" or "is withdrawn," and the Office Action can be read both ways. Applicants respectfully request clarification and reserve their comments at this time.

In regards to this rejection, it is worth noting that the Advisory Action dated May 24, 2002 states that the claims have not been amended to contain the transitional

phrase "consisting essentially of." In fact, the claims were amended to recited "coding sequences consisting of."

In view of the foregoing, the pending claims are seen to be in allowable condition.

Applicants' undersigned attorney may be reached in our Costa Mesa, California office by telephone at (714) 540-8700. All correspondence should continue to be directed to our address given below.

Respectfully submitted,

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